

# PCT COOPERATION TREATY

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

## PCT

WRITTEN OPINION

(PCT Rule 66)

To:

**ISHIHARA, Masanori**

**ISHIHARA & ISHIHARA**  
4F, Miyamasuzaka ST Building,  
8-6, Shibuya 1-chome  
Shibuya-ku, Tokyo 150-0002  
Japan

Date of mailing  
(day/month/year)

**14.01.03**

Applicant's or agent's file reference

**DP020708**

**REPLY DUE**

within **2 months** from  
the above date of mailing

International application No.

**PCT/JP 02/08389**

International filing date (day/month/year)

**20.08.02**

Priority date (day/month/year)

**29.01.02**

International Patent Classification (IPC) or both national classification and IPC  
Int.Cl<sup>7</sup>

**A61B 5/00 , A61B5/20 , A61B5/22**

Applicant

**NIHON UNIVERSITY**

1. This written opinion is the 1st (first, etc.) drawn by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I. ☒ Basis of the opinion
- II. ☐ Priority
- III. ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV. ☐ Lack of unity of invention
- V. ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI. ☐ Certain documents cited
- VII. ☐ Certain defects in the international application
- VIII. ☐ Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

**When?** See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

**How?** By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

**Also** For an additional opportunity to submit amendments, see Rule 66.4.  
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4bis.  
For an informal communication with the examiner, see Rule 66.6.

**If no reply is filed**, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is:

**29.05.04**

Name and mailing address of the IPEA/JP

**Japan Patent Office**

3-4-3, Kasumigaseki, Chiyoda-ku, Tokyo 100-8915, Japan

Authorized officer

**YOSHIHITO ITO**

Telephone No. +81-3-3581-1101 Ext. 3291

**2W**

**9604**



I. Basis of the opinion

1. With regard to the elements of the international application:\*

- ☐ the international application as originally filed
- ☒ the description:  
 pages 1-19, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☒ the claims:  
 Nos. 1-4, 6, 7, as originally filed  
 Nos. 5, as amended (together with any statement) under Article 19  
 Nos. \_\_\_\_\_, filed with the demand  
 Nos. \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☒ the drawings:  
 sheets/fig Fig. 1-7, as originally filed  
 sheets/fig \_\_\_\_\_, filed with the demand  
 sheets/fig \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the sequence listing part of the description:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/fig \_\_\_\_\_

5. ☐ This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed."

**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Claims	<u>3, 5 - 7</u>	YES
	Claims	<u>1, 2, 4</u>	NO
Inventive step (IS)	Claims	<u>3, 7</u>	YES
	Claims	<u>1, 2, 4 - 6</u>	NO
Industrial applicability (IA)	Claims	<u>1 - 7</u>	YES
	Claims		NO

**2. Citations and explanations**

The following document has been considered for the purpose of this report:

D1 = [JP 4-19862 B2]  
D2 = [JP 3151153 B2]  
D3 = [JP 3-54575 B2]

**1. Claims 1,2,4**

The subject matter of claims 1,2,4 does not appear to be novel with respect to the document D1 cited in the ISR. All the elements written in claims 1,2,4 were disclosed in D1.

**2. Claims 5,6**

The subject matter of claims 5,6 does not appear to involve an inventive step in view of the document D1 cited in the ISR and the document D2 cited in the same.

The inventions disclosed in D1 and D2 share the problem in that [measuring an elasticity of a human body]. The person skilled in the art would easily conceive the idea of applying the technical feature [a hardness detection sensor] employed in D2 to the invention disclosed in D1 by replacing a stress detection sensor in D1 with a hardness detection sensor in D2 in order to solve that problem.

**3. Claims 3,7**

The subject matter of claims 3,7 is neither disclosed in any of the documents cited in the ISR nor obvious to a person skilled in the art.

## ATTENTION

### Forms and Preparation Points for Documents to be Submitted

Forms for a written reply and a written amendment shall be prepared in conformity to Article 62 (Form 23) and Article 31 (Form 15) of Enforcement Regulations of Law Concerning the International Application of the Patent Cooperation Treaty and Related Matters.

#### [Remarks]

- The paper sheet used is set to Row A, No. 4 (horizontal writing 21cm, 29.7cm) of the Japanese Industrial Standards; only one side of a flexible, strong, smooth, lusterless, and durable paper sheet with no fold is used with its shorter side at the top; and unnecessary characters, signs, frame lines, ruled lines, etc. shall not be written on this paper.
- The paper shall be free of creases and tears.
- Margins shall be set to at least 2cm at the upper edge, the right edge, and the bottom edge of the paper sheet, and 2.5cm at the left edge. In principle, the margins shall not exceed 4cm at the upper edge and the left edge, or 3cm at the right edge and the bottom edge. In these cases, the margins are left completely blank. The document number (provided it is described in the request) may be added in the margin corner of the upper edge and within 1.5cm of the upper edge.
- The written reply shall be a typed or printed manuscript so that an arbitrary number of copies may be directly made by photograph, electrostatic method, photographic offset, or microfilm.
- In all the paper sheets of the written reply, serial numbers starting from 1 in Arabic numerals shall be added in the center of the top or bottom edge of the paper sheet (except for the margin parts).
- In cases of a typed manuscript, the space between the lines shall be set to at least 5mm. In case of using Roman letters in Remarks 11 and 14, the width shall be set to 1.5 letters.
- Items mentioned shall be written in characters of No. 4 type (Roman letters used for Remarks 11 and 14 are set to not less than 0.21cm in height in capital letters), wherein the color used shall be dark and non-fading, and the characters shall fulfill the requirements prescribed in Remark 4.
- In the column "Indication of International Application," where an applicant has already received the notification of the international application number from the Patent Office, the number shall be described in such a manner as "PCT/JP○○/○○○○○," where the applicant has not yet received the notification of the international application number, the date of submitting the international application shall be described in the order of date, month and year in such a manner as "international application submitted on ○○.○○.○○" (as for the year, only the last two figures of the Christian Era shall be described), and the document number (provided it is described in the request) shall be also described therein.
- The "Name of Applicant" shall be described as the full name in the order of family name and first name in the case of an individual person; in the case of a juridical body, the name shall be described.
- The "Address" shall be described in detail such as "Japan, prefecture, county, village, major article, minor article, plot number, and house number" and the postal code shall be also stated.
- The transliteration of the name and the address of the applicant or their translation into English shall be also added thereto using Roman letters.
- In the column "Nationality," the name of the country of the applicant or the representative shall be described.
- In the column "Address," the name of the country in which the applicant or the representative resides shall be described.
- In the case of describing the name of a country, the name of the country designated by the Commissioner shall be written in Japanese and English.
- In the column "Representative," the name of the representative shall be described and the applicable one from among "lawyer," "patent attorney," and "legal representative" shall be described before the name of the representative.
- Where a representative is stated, the seal of the applicant is not necessary; if there is no representative, the column "Representative" need not be provided.
- In each paper sheet, erasure, correction, overwriting, and inserted lines are not permitted in principle.
- The paper sheets for the written reply shall be filed with, for example, a clip so as to be easily separated or re-filed.
- In the "Address," only one address of each applicant, representative, attorney, or sub-attorney shall be described.
- In the column "Sub-Attorney," the name of the sub-attorney shall be described and the applicable name from among "lawyer" or "patent attorney" shall be described before the name of the sub-attorney.
- Where a sub-attorney is stated, the seal of an attorney is not necessary; if

- there is no sub-attorney, the column "Sub-attorney" need not be provided.
- The Christian Era or Gregorian Calendar shall be used for the date. Figures of the day, figures of the month, and last two figures of the year shall be expressed in Arabic numerals respectively in this order, and a period shall be added after the figures of the day and the month (for example, March 30<sup>th</sup>, 1978 shall be written as "30.03.78"). When using another era or calendar, the Christian Era or Gregorian Calendar shall be added thereto.

#### Form 23 (Related to Article 62)

##### REPLY(ARGUMENT)

To: Examiner of the Patent Office

##### 1. Identification of the International Application

##### 2. Applicant (Common Representative)

Name: seal

Address:

Country of Nationality:

Country of residence:

##### 3. Agent

Name: seal

Address

##### 4. Date of Notification

##### 5. Subject Matter of Reply(Argument)

##### 6. List of Attached Documents

#### [Remarks]

- In case an amendment is made pursuant to the order in the provisions of Article 6 of the Patent Law, the title shall be set to "AMENDMENT (amendment based upon the order in the provisions of Article 6 of said Law)"; in case an amendment is made pursuant to the provisions of Article 11 of said Law, the title shall be set to "AMENDMENT (amendment based upon the provisions of Article 11 of said Law)"; in case an amendment is made pursuant to the order in the provisions of Item 2 of Article 1 of the Patent Law Enforcement Order, the title shall be set to "AMENDMENT (amendment based upon the order in the provisions of Item 2 of Article 1 of said Order)"; in case an amendment is made pursuant to the provisions of Item 1 of Article 27-3, the title shall be set to "AMENDMENT (amendment based upon the provisions of Item 1 of Article 27-3)"; in case an amendment is made pursuant to the order in the provisions of Item 1 of Article 28, the title shall be set to "AMENDMENT (amendment based upon the order in the provisions of Item 1 of Article 28)"; in case a flexible disk is submitted pursuant to the provisions of Item 3 of Article 50-3, the title shall be set to "SUBMISSION OF FLEXIBLE DISK Based Upon the Provisions of Item 3 of Article 50-3"; in case a flexible disk is submitted pursuant to the order in the provisions of Item 5 of Article 50-3, the title shall be set to "SUBMISSION OF FLEXIBLE DISK Based Upon the Order in the Provisions of Item 3 of Article 50-3"; in case a document describing the sequence listing is submitted pursuant to the order in the provisions of Item 5 of Article 50-3, the title shall be set to "SUBMISSION OF DOCUMENT DESCRIBING SEQUENCE LISTING Based upon the Order in the Provisions of Item 5 of Article 50-3"; and in case an amendment is made pursuant to the order in the provisions of Item 8 of Article 50-3, the title shall be set to "AMENDMENT (amendment based upon the order in the provisions of Item 8 of Article 50-3)".
- If an examiner of the Patent Office has given an opportunity for submitting a written reply or its amendment, the reply or the amendment shall be submitted to said examiner of the Patent Office, and it shall be submitted to the Commissioner of the Patent Office for any other cases.
- In the column "Object of Amendment," the name of the document to be amended and the passage to be amended shall be described in such a manner as "Request II, Column of Applicant."
- In the column "Contents of Amendment," "as per an accompanying sheet" shall be described and the matters to be amended shall be pointed out, and a replacement paper sheet for the amendment shall be appended. However, where the whole of the paper sheet is deleted as a result of the amendment, where the amendment is made pursuant to the order in the provisions of Article 6 of the Patent Law, Item 2 of Article 1 of the Patent Law Enforcement Order, Item 1 of Article 28 or Item 8 of Article 50-33, or where the amendment is made pursuant to the provisions of Item 1 of Article 27-3, there is no need to use a replacement paper sheet if the matters related to the amendment can be easily re-written in the original text. Where a replacement paper sheet for an amendment provided for in Article 11 of the Patent Law is appended, and the matter related to the amendment is a deletion or an addition of only a part of a passage or a minor correction, the amendment may be made in the copy of the written amendment that has been submitted before instead of using a replacement paper sheet provided it does not affect the neatness and direct copying of the paper sheet.
- When the scope of claims is amended, a replacement paper sheet

describing the scope of claims related to said amendment as follows shall be appended.

- a) When a new item is added to the scope of claims, the number given to the last item of the scope of claims before being amended shall be described before the item to be added in such a manner as "○ (added)."
  - b) When any item of the scope of claims is deleted, the number given to the item of the scope of claims to be deleted shall be described in such a manner as "○ (deleted)."
  - c) When the scope of claims is amended without increasing or decreasing the number of items of the scope of claims, the same number as that for the item of the scope of claims before being amended shall be given to the amended item of the scope of claims in such a manner as "○ after being amended."
6. When a flexible disk is submitted pursuant to the provisions of Item 3 of Article 30-3 or when a flexible disk is submitted pursuant to the order in the provisions of Item 5 of Article 60-3, descriptions shall be made as follows.
- a) In the column "7. List of Attached Documents," the following items shall be described.  
5. List of Attached Documents
    - (1) Flexible disk that records code data concerning sequence listing: 1 piece
    - (2) Statement: 1 copy
    - (3) Document describing information about the recording method, etc. of a flexible disk: 1 copy
  - b) In principle, the "Statement" shall be prepared pursuant to the sample shown below. The item "Indication of International Application" shall be described pursuant to Remark 15 described hereunder.  
(Sample)  
STATEMENT  
To: the Commissioner of the Patent Office  
I hereby declare that the base sequence and amino acid sequence recorded in the flexible disk attached to this document have faithfully encoded the base sequence and amino acid sequence described in the specification without making any change of the contents.  
Day month, year  
Indication of International Application  
Title of the Invention  
Applicant or Agent
  - c) "Document describing information about the recording method, etc. of a flexible disk" shall be made, in principle, by providing and describing such items as "Name of Applicant," "Name of Agent," "Indication of International Application," "Title of the Invention," "Character Code Used," "Name of a File Recording the Sequence," and "Person to be Contacted (phone number and name of the person in charge)."
  - d) Columns "5. Object of Amendment" and "6. Contents of Amendment" shall not be provided.
7. When a document describing the sequence listing pursuant to the order in the provisions of Item 5 of Article 60-3, the following item shall be described in the column "7. List of Attached Documents," and columns "5. Object of Amendment" and "6. Contents of Amendment" shall not be provided.  
5. List of Attached Documents
  - (1) Document describing the sequence listing: 1 copy
8. The paper sheet used is set to Row A, No. 4 (horizontal writing 21cm, 29.7cm) of the Japanese Industrial Standards; only one side of a flexible, strong, smooth, lusterless, and durable paper sheet with no fold is used with its shorter side at the top; and unnecessary characters, signs, frame lines, ruled lines, etc. shall not be written on this paper.
9. The paper shall be free of creases and tears.
10. Margins shall be set to at least 2cm at the upper edge, the right edge, and the bottom edge of the paper sheet, and 2.5cm at the left edge. In principle, the margins shall not exceed 4cm at the upper edge and the left edge, or 3cm at the right edge and the bottom edge. In these cases, the margins are left completely blank. The document number (provided it is described in the request) may be added in the margin corner of the upper edge and within 1.5cm of the upper edge.
11. The written amendment shall be a typed or printed manuscript so that an arbitrary number of copies may be directly made by photograph, electrostatic method, photographic offset, or microfilm.
12. In all the paper sheets of the written amendment, serial numbers starting from 1 in Arabic numerals shall be added in the center of the top or bottom edge of the paper sheet (except for the margin parts).
13. In cases of a typed manuscript, the space between the lines shall be set to

at least 5mm. In case of using Roman letters in Remarks 11 and 14, the width shall be set to 1.5 letters.

14. Items mentioned shall be written in characters of No. 4 type (Roman letters used for Remarks 11 and 14 are set to not less than 0.21cm in height in capital letters), wherein the color used shall be dark and non-fading, and the characters shall fulfill the requirements prescribed in Remark 9.
15. In the column "Indication of International Application," where an applicant has already received the notification of the international application number from the Patent Office, the number shall be described in such a manner as "PCT/JP○○/○○○○○," where the applicant has not yet received the notification of the international application number, the date of submitting the international application shall be described in the order of date, month and year in such a manner as "international application submitted on ○○.○○.○○" (as for the year, only the last two figures of the Christian Era shall be described), and the document number (provided it is described in the request) shall be also described therein.
16. The "Name of Applicant" shall be described as the full name in the order of family name and first name in the case of an individual person; in the case of a juridical body, the name shall be described.
17. The "Address" shall be described in detail such as "Japan, prefecture, county, village, major article, minor article, plot number, and house number" and the postal code shall be also stated.
18. The transliteration of the name and the address of the applicant or their translation into English shall be also added thereto using Roman letters.
19. In the column "Nationality," the name of the country of the applicant or the representative shall be described.
20. In the column "Address," the name of the country of the applicant or the representative shall be described.
21. In the case of describing the name of a country, the name of the country designated by the Commissioner shall be written in Japanese and English.
22. In the column "Representative," the name of the representative shall be described and the applicable one from among "lawyer," "patent attorney," and "legal representative" shall be described before the name of the representative.
23. Where a representative is stated, the seal of the applicant is not necessary; if there is no representative, the column "Representative" need not be provided.
24. In each paper sheet, erasure, correction, overwriting, and inserted lines are not permitted in principle.
25. The paper sheets for the written reply shall be filed with, for example, a clip so as to be easily separated or re-filed.
26. In the "Address," only one address of each applicant, representative, attorney, or sub-attorney shall be described.
27. In the column "Sub-Attorney," the name of the sub-attorney shall be described and the applicable name from among "lawyer" or "patent attorney" shall be described before the name of the sub-attorney.
28. Where a sub-attorney is stated, the seal of an attorney is not necessary; if there is no sub-attorney, the column "Sub-attorney" need not be provided.
29. The Christian Era or Gregorian Calendar shall be used for the date. Figures of the day, figures of the month, and last two figures of the year shall be expressed in Arabic numerals respectively in this order, and a period shall be added after the figures of the day and the month (for example, March 30<sup>th</sup>, 1978 shall be written as "30.03.78"). When using another era or calendar, the Christian Era or Gregorian Calendar shall be added thereto.

Form 15 (Related to Article 31)

CORRECTION(AMENDMENT)

To: Commissioner of the Patent Office

(To : Examiner of the Patent Office)

1. Identification of International Application

2. Applicant (Common Representative)

Name: \_\_\_\_\_ Signature \_\_\_\_\_ (Seal)

Address:

Country of nationality:

Country of residence:

3. Agent

Name: \_\_\_\_\_ Signature \_\_\_\_\_ (Seal)

Address:

4. Date of Invitation

5. Item to be Corrected(Amended)

6. Subject Matter of Correction(Amendment)

7. List of Attached Documents